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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/386,850	08/31/1999	ISABELLE ROSINSKI-CHUPIN	004900-169	1870

21839 7590 11/20/2002

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ALEXANDRIA, VA 22313-1404

EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 11/20/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/386,850

Applicant(s)
Rosinski-Chupin et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 31, 1999 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

DETAILED ACTION

1. The request filed on June 17, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/386,850 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claim 17 has been canceled. Claims 15 and 16 are pending and under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. After review of applicants arguments and the prior art publications submitted July 28, 2002, the rejection of claims 15 and 16 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility is withdrawn; the rejection of claims 15 and 16 under 35 U.S.C. 112, first paragraph for lacking enablement due to the absence of a specific substantial asserted utility or a well-established utility is also withdrawn.
5. The specification is objected to as not complying with 1.821(d) of the Sequence Rules and Regulations. When the specification of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims of the patent application. The specification recites SMR1 on pages 1, 2, 5, 7, 8, 9, 10, 11 and 12. Appropriate correction is required.
6. This application contains sequence disclosures on page 2, lines 8, 10, 12, 16 and 18, page 2 line 25 to page 3, line 13, and page 11, lines 5, 12, 13 and 16-17, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 as no sequence identifiers have been provided for said sequences.

7. Claims 15 and 16 objected to as not complying with 1.821(d) of the Sequence Rules and Regulations. When the claims of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims of the patent application. Claim 15 and 16 recite SMR1 without the sequence identifier. Appropriate correction is required.

8. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites "nucleotide probe having the nucleotide sequence of SEQ ID NO:1". However, SEQ ID NO:1 is an amino acid sequence. In addition, the use of a nucleotide probe comprising the nucleic acids encoding SMR1 will result in hybridization to genomic sequences, not expressed sequences, as the nucleic acids encoding SEQ ID NO:1 are themselves expressed sequences.

Claim 15 recites "allowing said probe to hybridize with the target DNA or RNA molecule". The term "hybridize" is indefinite without a recitation of physical parameters of buffers, concentrations, temperatures and times.

Claim 15 and 16 recite "SMR1". SMR1 is a laboratory designation, the identify of which can be variable. Amendment of the claim to incorporate a sequence identifier will obviate this rejection.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an

application for patent by another filed in the United States before the invention by the applicant for patent except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the united states and was published under article 21(2) of such treaty in the English language.

10. Claim 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosinski-Chupin et al (PNAS 1988 November, Vol. 85, pp. 8553-8557). Claim 15 is drawn to a method for detecting or quantifying a nucleic acid coding for SMR1 comprising contacting a DNA or RNA molecule with a nucleotide probe complementary to the nucleic acids encoding the amino acid sequence of SEQ ID NO:1, and detecting the hybrid formed between the DNA or RNA and the probe. Claim 16 is drawn to a method according to claim 15 wherein polyadenylated mRNA is prepared from the submaxillary gland of a rat, said mRNA is subjected to gel electrophoresis, said mRNA is transferred to a nylon membrane, and contacted with a nucleotide probe which hybridized to the nucleic acids encoding SEQ ID NO:1, the hybrid formed between the probe and the RNA is detected and quantified. Rosinski-Chupin et al disclose a method of detecting the nucleic acids encoding SMR1 (page 8553, second column, under the heading "Cloning and characterization of the SMR1 cDNA, also page 8554, second column, under the heading "Isolation and Sequence of a cDNA complementary to a Rat Male-Specific mRNA") as well as the nucleic acids encoding the SMR1 protein which comprise the instant SEQ ID NO:1 (figure 3). Rosinski-Chupin et al also disclose all the specific embodiments of claim 16 (page 8554, first column, under the heading "RNA analysis"). The total RNA would contain polyadenylated mRNA. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

11. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Derynck et al (US 4,886,747) as evidenced by Accession Number AAQ03301 (1989). The specific embodiments of claim 15 are set forth above. Derynck et al disclose a method for detecting RNA wherein a lambda-beta C1 probe of 1050 bases to hybridize to the mRNA of TGF-beta. Accession Number AAQ03301 indicates that TGF-beta comprises nucleotide sequence encoding SEQ ID NO:1, from


residues 1874 to residues 1885, and thus would hybridize to a nucleotide probe complementary to the nucleic acids encoding the amino acid sequence of SEQ ID NO:1.

12. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Rajput et al (EP 0277,313 A1) as evidenced by Accession Number Accession Number A11237 (Dec, 1993). The specific embodiments of claim 15 are set forth above. Rajput et al disclose a method for detecting DNA wherein a 31-mer nucleotide probe used for colony hybridization (page 15, line 42-44, page 16, lines 7-8, and Figure 5. Accession Number A11237 indicates that this 31-mer has a nucleotide sequence which would hybridize to SEQ ID NO:1, thus fulfilling the specific embodiments of the claimed active method steps.

13. All claims are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 17, 2002


ANTHONY C. CAPUTA
CURRENTLY PATENT EXAMINER
TECHNOLOGY SECTION 1642